CLAIMS

In the claims:

1. A pharmaceutical composition having interferon-beta (IFN-β) activity and comprising a therapeutically effective amount of an isolated IFN-β mutein for treatment of multiple sclerosis (MS),

wherein said therapeutically effective amount is in a range that is greater than 375 mcg to at least about 500 mcg, and

wherein said IFN-β mutein has a cysteine at position 17 deleted or replaced by a neutral amino acid.

2. The pharmaceutical composition according to Claim 1, wherein said therapeutically effective amount is at least about 500 mcg to at least about 625 mcg.

3. The pharmaceutical composition according to Claim 1, wherein said therapeutically effective amount is at least about 450 mcg to at least about 550 mcg.

4. The pharmaceutical composition according to Claim 1, wherein said therapeutically effective amount is at least about 475 mcg to at least about 525 mcg.

5. The pharmaceutical composition according to Claim 1, wherein said therapeutically effective amount is about 500 mcg.

6. The pharmaceutical composition according to Claim 1, wherein said neutral amino acid is selected from a group consisting of serine, threonine, glycine, alanine, valine, leucine, isoleucine, histidine, tyrosine, phenylalanine, tryptophan, and methionine.

7. The pharmaceutical composition according to Claim 1, wherein said neutral amino acid is serine.

8. The pharmaceutical composition according to Claim 1, wherein said therapeutically effective amount is about 500 mcg and said neutral amino acid is serine.

9. The pharmaceutical composition according to Claim 1, wherein said IFN-β mutein lacks an N-terminal methionine.

10. The pharmaceutical composition according to Claim 1, wherein said IFN-β mutein is Betaseron®.

11. The pharmaceutical composition according to Claim 1, wherein said pharmaceutical composition is a stabilized, human serum albumin-free (HSA-free) pharmaceutical composition.

12. The pharmaceutical composition according to Claim 9, wherein said IFN-β mutein is substantially monomeric and solubilized in a low-ionic-strength formulation.

13. The pharmaceutical composition according to Claim 10, wherein said low-ionic-strength formulation is a solution having a pH from about 2 to about 5, and an ionic strength from about 1 to about 100 mM.

14. The pharmaceutical composition according to any one of Claims 1-11, wherein said IFN-β mutein is a human IFN-β mutein.

15. A method of treating a patient for multiple sclerosis comprising administering to said patient the pharmaceutical composition according to any one of Claims 1-11.

16. The method according to Claim 13, wherein said IFN-β mutein is a human IFN-β mutein.